Attachment 19

RAI SERVICES COMPANY

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VIA ELECTRONIC SUBMISSION
AND HAND DELIVERY

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-N-3065 ("Tobacco Products; Required Warnings for Cigarette Packages and Advertisements")

Dear Sir or Madam,

On August 16, 2019, the U.S. Food and Drug Administration ("FDA" or "the Agency") issued a proposed rule regarding graphic warnings for cigarette packaging and advertising. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements*, 84 Fed. Reg. 42,754 (Aug. 16, 2019). RAI Services Company ("RAIS") filed comments on the proposed rule, explaining that (among other things) FDA had failed "to release any information about its qualitative studies," which "were critical to the development of the proposed warnings." RAIS Comments, Docket No. FDA-2019-N-3065, Executive Summary at 5 (Oct. 11, 2019). On November 12, 2019, FDA placed additional materials regarding those qualitative studies in the docket. *See Tobacco Products; Required Warnings for Cigarette Packages and Advertisements; Additional Materials; Reopening of the Comment Period*, 84 Fed. Reg. 60,966 (Nov. 12, 2019). Specifically, FDA released four reports regarding "qualitative focus groups and interviews" that the Agency used "to test and refine image concepts and obtain feedback on which textual statements should be selected for further study." *Id.* at 60,967. FDA also "reopen[ed] the comment period for the proposed rule for 15 days to allow comment on the additional materials." *Id.* In response, RAIS respectfully submits these comments on its own behalf and on behalf of its affiliated tobacco companies.[1]

The additional materials confirm what should be clear to all objective observers: FDA designed the proposed warnings "to evoke negative emotions, such as fear, disgust, and distress,"

[1] RAIS coordinates regulatory compliance for Reynolds American Inc.'s ("RAI") subsidiary companies, including R.J. Reynolds Tobacco Company; American Snuff Company, LLC; Santa Fe Natural Tobacco Company, Inc.; and R.J. Reynolds Vapor Company. References to RAIS or "the Company" in this letter may refer to RAIS itself and/or its affiliated RAI subsidiaries, as applicable.

- **Macular-Degeneration Image**: FDA showed people an image of a "female receiving an injection in the eye to treat macular degeneration caused by smoking." *Id.* at 138. FDA said that this image "evoked visceral reactions and statements of discomfort from most participants." *Id.* In response to this image, people said the following:

    - "Do you see how long the needle looks? That looks scary." *Id.* at 142.

    - "Yes, it definitely would [grab my attention] because that's scary. That's scary. You can see the needle. Your eye is open and a needle is coming toward your eye, that's scary." *Id.*

    - "It's terrifying. I am terrified of needles, so this is my worst nightmare." *Id.*

As these interviews reveal, FDA knew—from the earliest stages of development—that the proposed warnings would evoke negative emotions and thereby convey an ideological, anti-smoking message. Despite that knowledge, FDA included each of these images in the proposed rule without making any meaningful changes to them. Indeed, in some cases, FDA made the images *more* gruesome—for example, FDA made the diseased lungs bloodier, and made the feet with the amputated toes more disfigured.

The additional materials are particularly troubling in light of FDA's assurances in the proposed rule that the Agency had addressed this issue. In *R.J. Reynolds Tobacco Co. v. FDA*, the D.C. Circuit held that FDA's first set of graphic warnings constituted "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting." 696 F.3d at 1217. In the proposed rule, FDA said that it had "carefully considered" that holding and gone through a "science-based, iterative research process" to "thoroughly address[] any such criticisms." 84 Fed. Reg. at 42,777–78. When FDA made that statement, it was obvious that the Agency's quantitative studies did not address the D.C. Circuit's concerns. *See* RAIS Comments at 6 ("[T]he proposed rule demonstrates that FDA did *nothing* to determine whether the proposed warnings evoke emotion or convey an anti-smoking message. FDA has published all three survey instruments that the Agency used to test the proposed warnings, and those surveys do not include a *single* question about whether the warnings evoke emotion or convey the message that people should not smoke."). Now, it is apparent that FDA's qualitative studies did not address the D.C. Circuit's concerns either. Indeed, nothing in the administrative record suggests that FDA gave a moment's thought to reducing the emotional and ideological nature of the proposed warnings. On the contrary, given that FDA knew about this problem and deliberately failed to address it, one can conclude only that FDA wanted the proposed warnings to have such an effect.

qualitative study, "[m]any participants were confused about the scar and the tubes and what type of surgery they indicate." Second Qualitative Study Report at 59.

- **COPD Warning Statement**: This warning confused some people who "did not know the meaning of 'COPD.'" First Qualitative Study Report at 19; *see also* Findings from Cognitive Testing of Spanish Warning Labels at 7 (Mar. 22, 2016) ("Four participants found the term COPD to be confusing.").

- **Erectile-Dysfunction Image**: People had a "wide variety of interpretations for this image." Second Qualitative Study Report at 70. Some people thought that the couple had a "strained relationship … because he smokes and she doesn't," while others thought the man was suffering from "[i]nsomnia/sleeplessness" or "[s]tress/depression." *Id.*

- **Amputated-Toes Image**: People found this image confusing because the "cause of the foot problem is unclear," the image did not seem "realistic," and the image was too "extreme." Second Qualitative Study Report at 67.

- **Macular-Degeneration Image**: When FDA first tested this image, people "could see that the eye was getting an injection," but they "could not understand why the injection was necessary." Image-Concept Report at 138. People thought this image was confusing even after it was paired with a textual warning statement because people "had never heard of macular degeneration and the image does not show what it is." Second Qualitative Study Report at 75.

Overall, people found the proposed warnings to be confusing. In its initial testing, FDA analyzed "how well participants understood the intended message" of ten graphic images that were later included, in similar form, in the proposed rule. Image-Concept Report at 13. For five of those images, FDA concluded that the message clarity was "low" (i.e., only a "[f]ew participants understand the intended message"). *Id.* at 13, 22, 77, 126, 138, 143. And for two more images, FDA concluded that the message clarity was "medium" (i.e., only "[s]ome participants understand the intended message"). *Id.* at 13, 61, 121.

The additional materials also reveal that many people found the proposed warnings to be misleading:

- **"Causes"**: The "most prevalent finding" in FDA's first qualitative study was that people found "statements of the type 'X causes Y'" to be misleading. First Qualitative Study Report at 52. Instead, people thought that statements would be more accurate if they said "'can cause,' 'may cause,' or 'increases the risk of' instead of 'cause' or 'causes.'" *Id.*; *see also id.* at 15, 17, 19, 26, 27, 31, 33, 34, 35, 36, 38, 45, 46.